

Clinical study using Monivent Neo100 published in Resuscitation

A clinical study showing significant improvement of the quality of manual ventilation of newborns in need of respiratory support using the Neo100 was finalized last year. The clinical paper on the results from this trial has now been accepted to be published in the highly renowned journal Resuscitation and is already available at resuscitationjournal.com. Resuscitation is an international and interdisciplinary medical journal for research relating to acute care medicine and cardiopulmonary resuscitation and recognized by the European Resuscitation Council as its official Journal.

The clinical study, “Optimization of manual ventilation quality using respiratory function monitoring in neonates: A two-phase intervention trial”, was conducted by Dr Robyn Dvorsky and the research team led by Dr Michael Wagner at the Medical University Hospital in Vienna. The results of the clinical study, including 90 newborns, show that the use of Neo100 significantly increased the quality of ventilations by a higher percentage (53.7%) occurring within a target volume range in the group with visible monitor and feedback compared to the control group without feedback (37.3%). Furthermore, excessive tidal volumes, which have been previously associated with an increased risk of brain injury, as well as mask leakage, which may impact the ability to deliver air to the baby’s lungs, could be significantly reduced. The equipment was used for newborn resuscitation in the delivery room and during elective intubation in the neonatal intensive care unit. The results from the trial were first presented at the Pediatric Academic Societies (PAS) annual meeting in Washington in May 2023.

”The acceptance of the article by such well recognized journal is a strong indicator for the high level of interest in respiratory support for newborns and confirms the quality of the research done by the team in Vienna. The results demonstrate the benefits that can be achieved having access to real-time objective feedback during manual ventilation, proving that we have successfully developed a device that is user-friendly and easy to interpret, even in stressful situations. Solid clinical evidence is crucial for entering new markets and also for hospitals to decide on new equipment, and these excellent results will greatly support the further commercialization of the Neo100”, says Maria Lindqvist, CEO of Monivent.

“We hypothesized that visual feedback on ventilation parameters supports providers evaluating ventilation quality in real-time and enables necessary adjustments. In this trial, we chose to use the Monivent Neo100 due to its easy-to-interpret interface with numerical display of only five key ventilation parameters and a color-coded graphical display of the tidal volume. We believe that the user-friendliness was a strong contributing factor to our positive findings. Our results suggest that the clinical use of Neo100 in preterm and term infants leads to a significant improvement in manual ventilation, which may have a positive impact on the future care for those newborn babies”, says Dr Michael Wagner, Medical University of Vienna.

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***Monivent AB** (“Monivent”) develops, manufactures and sells medical devices in order to improve the emergency care provided to newborns in need of respiratory support at birth. About three to six percent of all newborns end up in this critical situation and healthcare professionals today lack good tools to determine how effective this manual ventilation is. Monivent has developed equipment that measure the airflow to the child directly in the face mask via a sensor module that sends data wirelessly to an external monitor. The caregiver thereby receives immediate feedback, which enables necessary adjustments to support an effective but at the same time gentle treatment. The company is also marketing a product for simulation-based training on manikins, building on the same technology as the clinical product. The clinical product, Monivent Neo100, is not available for sale in the United States.*